

SPL ER/DL Subteam Meeting Minutes

June 6, 2012

Chair: Jessica Dunn Skorupski

1. Brief Status Update D&B Validator Lite, Validation Confidence Level Definitions – Jessica Skorupski

- We are making progress outlining the design of the “DUNS Validator Lite” application, as well as working through the initial development cycle. From a timing perspective, we are looking at an early – mid June timeline for having a beta version ready for testing with SPL pilot group.
- D&B has a rather complex entity matching process that is used to support all of our entity matching applications, including DUNS Validation. The entity matching process is comprised of several steps including input data normalization, parsing and word standardization followed by match candidate evaluation and scoring. The output of the D&B match process includes the assignment of a D&B Confidence Code. The D&B Confidence Code ranges from 1 – 10 with 1 representing the lowest quality match and 10 representing the highest quality match.
- For illustrative purposes, as well as to reinforce the importance of synchronizing data with the D&B database, we described Confidence Code 10 matches as “nearly a character for character” match during some of the SPL meetings. That said, D&B does not assign verbal descriptions to the Confidence Code range. For example, a Confidence Code 10 match can be achieved without being character for character (the input record may have “inc.” abbreviated and the D&B record may have the “incorporated” spelled out, and D&B match technology diagnoses that inc. is the abbreviation for incorporated. So, we are not able to provide verbal description with the SPL group, because we do not use them. Rather, we utilize the number scale to represent the quality of the match.
- Regarding your second question, we currently have standard data resolution services that we would recommend using to resolve data discrepancies between industry data and the D&B database. These would include using the standard customer support service (either via telephone or internet) and utilizing an existing D&B contract (assuming the firm has a relationship with D&B).

2. Assigning NDC numbers for APIs that are shipped from domestic sites - Dale Iannetti

- It is my understanding that a NDC number is not required when shipping an API from our domestic sites within the US. Does someone know where is stated in any of the regulations? We have a FDA inspector at one of our US sites requesting a NDC number for an API.
- FDA inspector at Puerto Rico site for domestic API. Inspector wanted regulation that states that an NDC is not needed for bulk API manuf. In US. Thinks FDA may have wanted the NDC for the finished product.

3. Assigning Multilevel Packaging NDCs – Kathy Lins

We have heard from FDA regarding assigning NDC numbers for the different packaging levels for **CDER** products, and are being told that we need a different NDC number for the case level vs. the individual unit. See example below.

Packaging section of R3 file on Daily Med looks like this:

PACKAGING

#	NDC	Package Description	Multilevel Packaging
1	0409-7974-08	4 BAG In 1 CASE	contains a BAG
1		3000 MILLILITER In 1 BAG	This package is contained within the CASE (0409-7974-08)

Hospira is converting to r4 and added an additional packaging level of 1 BAG/1 POUCH:

Packaging

#	Item Code	Package Description
1	NDC:0409-7974-08	4 POUCH (4 POUCH) in 1 CASE
1		1 BAG (1 BAG) in 1 POUCH
1		3000 mL in 1 BAG

In response to the request for a manual override, we received this from FDA:

The NDC is for the inner package but you include it at the case level. The label image is for the 3000 ml bag. It has the NDC 0409-7974-08. In the data elements, this NDC is used for the case of 4 bags. There should be a different NDC for the case of 4 bags.

Please note this is an ANDA and is a CDER product, not a CBER product

We didn't believe this is applicable to CDER products. Hospira uses the same NDC for single item and carton of 4.

Several companies have submitted inquiries to FDA regarding the way NDCs are applied. When inquiries come into FDA, then FDA has to act. Is the case an actual shipping container or a saleable unit?

This question stems from downstream users of the data.

In this case of 4 is the salable unit but is a shipping container. Does the carton have a principal display panel – NO, it's a shipper label. The shipper case is not considered FPL to the Review Division. Hospira doesn't send the shipper label to the . The case is not in the How Supplied so that is why the Review Division is not aware so didn't ask ever for this as FPL.

NCPDP –

The 4 count is the only saleable unit.

In the barcode rule, the NDC preamble FRN and 201.25.

Can be confusing if someone scans and it says 1 pouch but it's really a 4 case.

CDER's interpretation of bar code rule, NDC is at unit of use. Preamble and FRN packages specific NDC to represent the actual package. There should not be 2 package codes that are the same for each product. FDA is looking at the rule for CBER b/c trying to write the validation rules for syringe within pouch and whether or not there should be an NDC for each the syringe and pouch individually. If vial is too small, there could be only on the outer ?? FDA is reading this VERY carefully to understand. Review division and CBER is looking at each level of . Veda perkins said this will be added to the review.

CDER not validating at that level at this time. Animal drugs not really part of the bar code rule. Cannot say if the validation procedure will eventually extend to CVM and CDER.

4. NDC labeler code question –

The company has a labeler code and is a relabeler and importer of Mexican products (no manfg.) last person to handle product. Should they use their labeler code or the mfg labeler code.

- Products regulated by CDER. Hand creams deodorants.
- On SPL, the company uses the original NDC code from the mfg.
- From SPL perspective – if the product is regulated by CDER, both NDCs should be included.
- Mfg for private labeler distributor, mfg should include their NDCs in the file as OTC unapproved, or mfg exclusively for PLD. Then the distributor would also list.
- Arrangement can be made by the partnerships.
- The NDC on the product is not matching the NDC used by the mfg. co.
- Send examples and the links to Dailymed products to SPL email .

5. Update from FDA – for a very small segment of companies.

Will be discussed also at tech team meeting. Certain product ISBT – international standard for blood transfusions.

- Instead of NDCs CFR 207. Ie, cord blood.
- In SPL file, ISBT code and CBER has granted an exemption from the NDC requirement.
- Facility code and product code filed. Facility ID and product code have to be developed as separate fields. Software should hyphenate so this appears at the package code only, there will be not . CBER feels strongly about these 2 fields.
- New doc type is on the website and in the system validation. License minimally manipulated cells.
- Should still submit a labeler.
- Facility is registered through CBER as drugs so the ERs are registered as normal.
- Do you need to register the facility ID as it is a labeler code? Yes. May include a letter in the name.
- Must submit a labeler code request and include a facility ID. Pragmatic Validator lite is not yet updated. Not many products.

6. Methytrexate unapproved drug for use in an shortage.

- NDC Hospira assigned was previously used for a product discontinued in 2002. Need to apply a new NDC. Should Hospira just update the SPL with the new NDC?
- Hospira's government reporting group cannot reuse the previous NDC.
- This old product is off the market. The product was sold to Maine pharma. NCPDP has associated this new NDC with this product. The SPL file will have to be corrected in the SPL file and then a manual override requested with the justification. Do not create a whole new table?
- Just the product code is changing in metadata and packaging section. Issue was on CMS end, FDA allows reuse after 5 years but CMS does not. Other entities also have an issue with reuse.
- From a non legal perspective there is a 5 year reuse in the regulations. 207 regs.